

**Response and Amendment under 37 C.F.R. § 1.111**  
**Application No. 09/970,020**  
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**III. Remarks**

After entry of the amendment, claims 24-54 are pending.

Claims 1-23 have been canceled without prejudice. Claims 24-54 are supported by the originally filed claims and the specification at, for example, page 22, line 24 to page 23, line 2; and page 34, lines 1-5.

**A. Rejection under 35 U.S.C. § 112**

Claims 4-5, 14-15 and 21-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Upon review of the trademark database at [www.uspto.gov](http://www.uspto.gov), one skilled in the art would know that Prosolv® is the trademark for a silicified microcrystalline cellulose (Exhibit A); Expotab® is the trademark for a sodium starch glycolate (Exhibit B); and that TIMERx® is the trademark for a heteropolysaccharide and polysaccharide gum excipient (Exhibit C).

In view of the newly submitted claims, Applicants respectfully submit that the rejection is now moot.

**B. Rejections under 35 U.S.C. § 102 and § 103**

Claims 1-3, 6-13 and 16-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by and under 35 U.S.C. § 103 as being obvious over Gilbert et al (WO 98/40053).

In view of the newly submitted claims, Applicants respectfully submit that the rejection is moot.

**C. Rejection under 35 U.S.C. § 103**

Claims 4, 5, 14, 15 and 21-23 are rejected under 35 U.S.C. § 103 as being obvious over Gilbert (WO 98/40053) in combination with Baichwal et al (US Patent No. 4,994,275).

Applicants respectfully traverse the rejection and respectfully submit that the claims are unobvious over the combination of cited references and that the PTO has not established a *prima facie* case of obviousness.

The PTO asserts that any conventional controlled-release technology can be used to achieve the desired tablet formulation and admits that Gilbert does not expressly teach the TIMERx® formulation.

On May 6, 2003, a review of the patents in the PTO database from 1976 to May 6, 2003, at [www.uspto.gov](http://www.uspto.gov) revealed 22,097 hits for a boolean search of "controlled," "release," and

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"pharmaceutical;" **17,479** hits for a boolean search of "sustained," "release," and "pharmaceutical;" and **11,214** hits for a boolean search of "extended," "release," and "pharmaceutical."

If Gilbert teaches that any conventional controlled-release technology can be used and Gilbert does not teach TIMERx®, Applicants respectfully request to be advised why one skilled in the art would be motivated to select the Baichwal et al reference among the more than 22,000 patents from 1976 to the present in the PTO database that describe conventional controlled-release technology. Applicants respectfully submit that this rejection is improperly based on a hindsight review of the references.

Baichwal et al describe sustained release excipients. Baichwal et al do not disclose or suggest that the sustained release excipients could be used for pharmaceutical compositions comprising a combination of immediate release formulations and controlled release formulations; and does not disclose or suggest that the sustained release excipients could be used for pharmaceutical compositions where the (+) and (-) chiral enantiomers are separated in the formulation. There is simply no motivation for one skilled in the art to use the sustained release excipients described by Baichwal et al in the formulation described by Gilbert.

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

**IV. Conclusion**

An early and favorable consideration and allowance of claims 24-54 is respectfully requested.

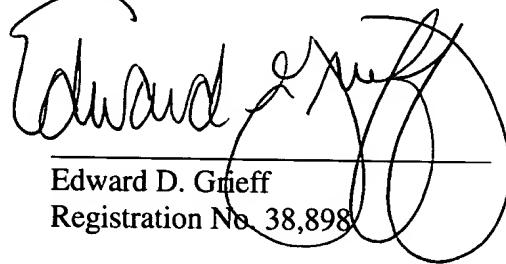
No fees are believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219.

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The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

HALE AND DORR LLP



A handwritten signature in black ink, appearing to read "Edward D. Grieff". The signature is fluid and cursive, with some loops and variations in style.

Edward D. Grieff  
Registration No. 38,898

Date: May 8, 2003  
HALE AND DORR LLP  
60 State Street  
Boston, MA 02109  
Phone: 202-942-8400

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# Exhibit A



## UNITED STATES PATENT AND TRADEMARK OFFICE

## Trademark Electronic Search System (TESS)

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**Start**List At:  OR **Jump** to record:  Record 3 out of 6**Check Status***(TARR contains current status, correspondence address and attorney of record for this mark. Use the "Back" button of the Internet Browser to return to TESS)***Typed Drawing****Word Mark** PROSOLV**Goods and Services** IC 001. US 001 005 006 010 026 046. G & S: Silicified microcrystalline cellulose for use in the manufacture of pharmaceutical preparations, nutritional supplements, and nutritional foodstuff preparations. FIRST USE: 19970107. FIRST USE IN COMMERCE: 19970107

IC 030. US 046. G &amp; S: Food additives for non-nutritional purposes for use as a flavoring, ingredient or filler food. FIRST USE: 19970107. FIRST USE IN COMMERCE: 19970107

**Mark Drawing Code** (1) TYPED DRAWING**Serial Number** 75839223**Filing Date** November 3, 1999**Published for Opposition** August 21, 2001**Registration Number** 2505862**Registration Date** November 13, 2001**Owner** (REGISTRANT) PENWEST PHARMACEUTICALS CO. CORPORATION WASHINGTON 2981 Route 22 Patterson NEW YORK 12563**Attorney of Record** Michael R. Graham**Prior**

**Registrations** 2223135;2237290  
**Type of Mark** TRADEMARK  
**Register** PRINCIPAL  
**Live/Dead Indicator** LIVE

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# Exhibit B



## UNITED STATES PATENT AND TRADEMARK OFFICE

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### Typed Drawing

**Word Mark** EXPLORATION  
**Goods and Services** IC 005. US 018. G & S: DISINTEGRATING AGENT IN COMPRESSED TABLET FORMULATIONS COMPRISING SODIUM STARCH GLYCOLATE. FIRST USE: 19710500. FIRST USE IN COMMERCE: 19710500  
**Mark Drawing Code** (1) TYPED DRAWING  
**Serial Number** 73068445  
**Filing Date** November 10, 1975  
**Registration Number** 1097160  
**Registration Date** July 25, 1978  
**Owner** (REGISTRANT) EDWARD MENDELL CO., INC. CORPORATION NEW YORK ROUTE 52 R.D. 5 CARMEL NEW YORK 10512  
**Assignment Recorded** ASSIGNMENT RECORDED  
**Attorney of Record** MICHAEL R GRAHAM  
**Type of Mark** TRADEMARK  
**Register** PRINCIPAL  
**Affidavit Text** SECT 15. SECT 8 (6-YR).  
**Renewal** 1ST RENEWAL 19980714  
**Live/Dead Indicator** LIVE

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# Exhibit C



## UNITED STATES PATENT AND TRADEMARK OFFICE

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# TIMERx

<b>Word Mark</b>	<b>TIMERX</b>
<b>Goods and Services</b>	IC 001. US 006. G & S: heteropolysaccharide and polysaccharide gum excipient used in the manufacture of time-release pharmaceutical preparations. FIRST USE: 19940912. FIRST USE IN COMMERCE: 19940912
<b>Mark Drawing Code</b>	(5) WORDS, LETTERS, AND/OR NUMBERS IN STYLIZED FORM
<b>Serial Number</b>	74137028
<b>Filing Date</b>	February 7, 1991
<b>Filed ITU</b>	FILED AS ITU
<b>Published for Opposition</b>	December 24, 1991
<b>Registration Number</b>	1920597
<b>Registration Date</b>	September 19, 1995
<b>Owner</b>	(REGISTRANT) EDWARD MENDELL CO., INC. CORPORATION WASHINGTON 2981 Route 22 Patterson NEW YORK 12563  (LAST LISTED OWNER) PENWEST PHARMACEUTICALS CO.

CORPORATION BY ASSIGNMENT, BY ASSIGNMENT, BY CHANGE OF  
NAME WASHINGTON 2981 ROUTE 22 PATTERSON NEW YORK 12563

**Assignment Recorded** ASSIGNMENT RECORDED  
**Attorney of Record** MICHAEL R. GRAHAM  
**Type of Mark** TRADEMARK  
**Register** PRINCIPAL  
**Affidavit Text** SECT 15. SECT 8 (6-YR).  
**Live/Dead Indicator** LIVE

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<a href="#">CURR LIST</a>	<a href="#">NEXT LIST</a>	<a href="#">FIRST DOC</a>	<a href="#">PREV DOC</a>	<a href="#">NEXT DOC</a>	<a href="#">LAST DOC</a>				